



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

Hodgen et al.

Examiner: Webman, E

Serial No.: 08/462,703 *PH*

Group Art Unit: 1617

Filed: June 5, 1995

For: ANTIPROGESTIN METHOD AND KIT FOR REDUCING SIDE EFFECTS ASSOCIATED WITH LOW DOSAGE HRT, ORAL CNTRACEPTION AND REGULATING MENSES

#43
Supp
11-28-01

REPLY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the office action dated May 22, 2001, please amend the above-identified application as follows:

? The Examiner is correct in that the undersigned made an unintentional misstatement in prior responses. It is true that both E+P and AP modalities block ovulation.

The Examiner appears to base the rejection on the fact that E+P, AP, and P are all individually known for fertility control. The allegation is that it would be obvious to combine any of these to achieve fertility control. However, this argument ignores what is being claimed.

Initially, it appears that claims 45 - 47 and 51-53 were not intended to be included in the rejection. These claims are drawn to HRT and not fertility control. The Examiner has already allowed the HRT aspects.

As for the remaining claims (42-44, 48-50, 54, 55, and 102-107), each of these recites an element not even suggested by the prior art.

Claims 42-44, 48-50, 54, and 55 each require that the amount of AP be "effective to ameliorate uterine bleeding control problems." Nothing in either of the references hints that either E+P birth control or P birth control could have their associated bleeding problems ameliorated by administration of any amount of AP. With respect to this amelioration effect see, e.g., page 19, lines

(1)

Refer to 1236?

unexpected based on the prior art.

As for the P+AP modality, see USP 5,622,943, of record, which has claims drawn to the same concept of minimizing uterine bleeding in a P- only preparation by administering an effective amount of an AP. The '943 example alleges to prove such results. While the existence of this patent establishes *prima facie* the patentability of the corresponding claims in this application it, of course, also illustrates the necessity for an interference between this patent and this application.

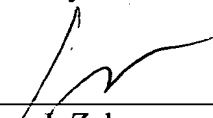
As for claims 102-107, the new element here is the unexpected menses induction effect mentioned above and established in the specification.

As to the Examiner's rejection based on USP 5468736, note that this patent is not commonly assigned with the current application. Consequently, a Terminal Disclaimer is not in order. Rather, an interference is the proper procedure.

Finally, as to the overlap of this application with the mentioned co-pending application, the same reason proffered previously for the propriety of the overlap still exists. Again, the proper procedure here is the institution of interferences with the '736 patent as well as the '943 patent. In this regard, the Examiner is referred to recent correspondence in related application 08/115,008.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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